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July 25, 2025

The Honorable Zahid N. Quraishi
United States District Court, District of New Jersey
402 East State Street
Trenton, NJ 08608

Re: *Elizabeth Pennell v. Novo Nordisk A/S, et al.*, 3:25-cv-02756
Plaintiff's Response to Defendants' Pre-Motion Letter

Dear Judge Quraishi:

Plaintiff Elizabeth Pennell submits this letter in response to Defendants' letter dated July 18, 2025.

Background

Ms. Pennell suffered permanent vision loss due to Defendants' Ozempic semaglutide drug.

Nonarteritic Anterior Ischemic Optic Neuropathy ("NAION") is a rare, irreversible condition, which causes permanent and sudden loss of vision. Vision is a necessity for independently accomplishing many daily tasks, is the most dominant of the senses, and is an integral aspect of the human experience. Because Ms. Pennell developed NAION from Novo's drugs, she suffers from significant vision loss in one eye. This has dramatically restricted Ms. Pennell's ability to travel independently, and limited her ability to read. Ms. Pennell is also reasonably fearful of losing her vision entirely. Ms. Pennell will suffer from vision loss for the rest of her life.

Novo's Ozempic semaglutide drug is unreasonably dangerous because it can cause sudden, permanent vision loss. Novo knew of this risk, and decided not to warn patients or their doctors. Novo instead engaged in an overwhelming marketing campaign – including hundreds of millions of dollars in payments to doctors, key opinion leaders, advocacy and lobbying groups, and advertising – intended to create the false impression that Ozempic does not carry serious risks such as those suffered by Ms. Pennell.

Since the publication of the Hathaway et al. paper in JAMA last August[1] finding a 660% increased risk of NAION with semaglutide, several other authors have explored the relationship between GLP-1 RA drugs and NAION.[2] These published reports and studies include epidemiological studies across tens of thousands of patients showing strong evidence of increased risk of NAION among GLP-1 RA users, as well as case reports of patients who developed NAION while using a GLP-1 RA drug whose condition

[1] *See* JT Hathaway, et al., *Risk of Nonarteritic Anterior Ischemic Optic Neuropathy in Patients Prescribed Semaglutide*, JAMA Ophthalmol., 142(8):732-739, dated Aug. 1, 2024, https://jamanetwork.com/journals/ jamaophthalmology/fullarticle/2820255.

[2] Hsu et al. (2025*) Semaglutide and Nonarteritic Anterior Ischemic Optic Neuropathy Risk Among Patients With Diabetes*; Grauslund et al. (2024) *Once-weekly semaglutide doubles the five-year risk of nonarteritic anterior ischemic optic neuropathy in a Danish cohort of 424,152 persons with type 2 diabetes;* Simonsen et al. (2025), *Use of semaglutide and risk of non-arteritic anterior ischemic optic neuropathy: A Danish-Norwegian cohort study;* Cai et al. (2025), *Semaglutide and Nonarteritic Anterior Ischemic Optic Neuropathy;* Katz et al. (2025), *Ophthalmic Complications Associated With the Antidiabetic Drugs Semaglutide and Tirzepatide.*

improved when the drugs were withdrawn, and declined when the drugs were re-introduced – which provide further substantial evidence of a causal association.[3]

Novo could have warned of this risk of NAION, but chose not to. Under the Changes Being Effected (CBE) regulation, a drug company may, without prior FDA approval, change its label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" based on "newly acquired information" where that information constitutes "evidence of a causal association" between the drug and a risk of harm. 21 CFR § 314.70(c)(6)(iii)(A). Novo's decision to hide this risk caused Plaintiff's injury.

Argument

Defendants' arguments ignore Ms. Pennell's well-pled allegations and disregard the basic tenets of notice pleading

Failure to Warn: Plaintiff's failure-to-warn claims do not rely solely upon a duty for Novo to warn Ms. Pennell directly, and Defendants' arguments fall flat. Defendants' reliance on North Carolina's Products Liability Act (PLA) is misplaced, as that provision protects the manufacturer only "if an adequate warning or instruction has been provided to the physician." N.C. Gen. Stat. § 99B-5(c). Ms. Pennell specifically alleges that Novo failed to warn her healthcare provider,[4] and thus adequately pleads a failure to warn claim consistent with North Carolina law.

Negligence: Defendants' attacks on Plaintiff's negligence claims should be rejected. A negligence claim requires allegations of a legal duty, breach of that duty, and a causal relationship between the breach of duty and injury sustained by the plaintiff. *Peace River Elec. Coop. v. Ward Transformer Co.*, 449 S.E.2d 202, 214 (N.C. App. 1994) (listing the elements for a North Carolina negligence claim). Plaintiff adequately alleged Defendants' duty,[5] and the causal relationship between Novo's breach of that duty and her injury.[6] Defendants' reliance on *Asby* is also misplaced. The *Asby* Court dismissed specific negligence claims that were substantially identical to other dismissed claims, not solely based on being "redundant" as Novo argues. *Asby v. Medtronic, Inc.*, 673 F. Supp. 3d 787, 795 (E.D.N.C. 2023).

Fraud and Misrepresentation: Defendants' attacks on Plaintiff's claims for fraud and misrepresentation miss the mark. To plead a claim for fraud, a plaintiff must allege particularly (1) a false representation or concealment of material fact, (2) reasonably calculated to deceive, (3) made with intent to deceive, (4) which does in fact deceive, and (5) resulting in damages to the injured party. *Hudgins v. Wagoner*, 694 S.E.2d 436, 442 (N.C. App. 2010); *see also Hunter v. Guardian Life Ins. Co. of Am.*, 593 S.E.2d 595, 598 (N.C. App. 2004) ("It is sufficient if, upon a liberal construction of the whole pleading, the charge of fraud might be supported by proof of the alleged constitutive facts."). Plaintiff clearly alleges Novo's knowledge of the label's falsity and Novo's intent to conceal such risks.[7] Plaintiff further pled the content of Defendants' fraudulent misrepresentation (the difference between what Defendant knew and what they said), its materiality, the mediums through which it was communicated, Defendants' intent to deceive, Plaintiff's and her prescribing doctor's reliance, and the misrepresentation's causal relationship to the resulting injury.[8] Moreover, "[a]s several courts have noted, Rule 9(b)'s 'heightened pleading

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[3] *See* Katz et al. at 4.
[4] *See, e.g.*, Compl. ¶ 299 ("had Plaintiff's prescribing healthcare providers been warned of the increased risk of NAION …the prescribing healthcare providers would not have prescribed Ozempic[.]").
[5] Compl. ¶ 424; *see also id.* at ¶¶ 455, 278, 287.
[6] *See, e.g.*, Compl. ¶¶ 299, 300.
[7] *See, e.g.*, Compl. ¶¶ 414-415.
[8] Compl. ¶¶ 408-418; *see Morganroth v. Norris, McLaughlin & Marcus, P.C.*, 331 F.3d 406, 414 n.2 (3d Cir. 2003) ("The purpose of Rule 9(b) is to provide notice, not to test the factual allegations of the claim").

standard is somewhat relaxed in a case based on a fraudulent omission,' rather than one based on misrepresentation."[9] Plaintiff's allegations satisfy the standard and successfully state a claim.

Express Warranty: To state a claim for express warranty in North Carolina, a plaintiff must allege that (1) an express warranty was made as to a fact or promise relating to the goods, (2) that the plaintiff relied on the warranty, and (3) that the defendant breached the expressed warranty. *Ascot Corp., LLC v. I&R Waterproofing, Inc.*, 881 S.E.2d 353, 359 (N.C. App. 2022). Defendants overreach in claiming that *Avandia* holds that warranties of safety or efficacy can never be actionable. *In re Avandia Mktg., Sales Pracs. & Prods. Liability Litig.*, 588 F. App'x 171, 176-77 (3d Cir. 2014). Unlike the claims in *Avandia*, Ms. Pennell's express warranty claims are not based solely on Ozempic's labels and packaging. *See* 588 F. App'x at 178 (noting representations were "in one source—Avandia's 'labels and packaging'"). As the Third Circuit noted in *Avandia*, other courts have permitted express warranty claims regarding safety and efficacy to proceed where representations were made beyond the label itself. *Id.* Here, Plaintiff alleges throughout the Complaint that Defendants promoted Ozempic's safety through a multi-faceted, multi-pronged approach in multiple settings.[10] These examples of affirmations by Defendants, upon which Plaintiff relied,[11] meets what is required for a breach of express warranty claim.

Negligent Undertaking: Defendants' argument that Plaintiff's negligent undertaking claim is barred by the learned intermediary doctrine mischaracterizes the basis for Defendants' duty. Novo voluntarily assumed an additional duty, not applicable to all manufacturers, when it embarked on its aggressive, direct-to-consumer campaign in relation to its Ozempic semaglutide drug.[12] Plaintiff adequately pleads Novo's failure to exercise reasonable care in that undertaking.[13]

Design Defect: Defendants provide only a general preemption standard, failing to acknowledge the well-settled exceptions applicable here, and ignoring the theory of liability that Plaintiff pled. Although a claim that would require Defendants to reformulate their drugs to comply with state law may be preempted by the FDA's approval proves, the Supreme Court has been clear that state law may impose a duty upon a pharmaceutical manufacturer to strengthen warnings, and that such warnings may be "the only way for [Defendants] to ameliorate the drug's 'risk-utility' profile – and thus to escape liability[.]" *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472, 484 (2013); *see also In re Fosamax Prods. Liab. Litig.*, 118 F.4th 322, 355 (3d Cir. 2024) ("because 'federal law – the FDA's CBE regulation – permits drug manufacturers to change a label… without prior approval from the FDA[,]… a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both.'") (quoting *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 314-15 (2019)). Moreover, Defendants do not contend that any warning on NAION was proposed by Defendants, or rejected by the FDA, and thus have no basis to argue that federal law rendered compliance with Defendants' state law duties impossible.

More Definite Statement: Defendants' request for a more definite statement seeks information about where relevant events occurred, which is beyond what Rules 8 and 12(e) require and should be denied. The standard for a Rule 12(e) motion for a more definite statement is "unintelligibility, not lack

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[9] *Majdipour v. Jaguar Land Rover N. Am., LLC*, No. 2:12-CV-07849 WHW, 2013 WL 5574626, at *15 (D.N.J. Oct. 9, 2013) (quoting *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 451 (D.N.J. 2012).

[10] *See, e.g.*, Compl. ¶ 347, ¶¶ 130-132 (describing Novo's multiprong promotional approach), ¶¶ 176-197 (describing Novo's extensive advertising), ¶¶ 204-210 (describing partnerships with telehealth providers).

[11] *See, e.g.*, Compl. ¶ 358 ("Plaintiff and Plaintiff's prescribing healthcare providers, as well as members of the medical community, relied on the express representations of Defendants[.]").

[12] *See, e.g.*, Compl. ¶ 492.

[13] *See, e.g.*, Compl. ¶¶ 496-498.

of detail." *Gittens v. Experian Info. Sols., Inc.*, 2014 WL 1744851, at *2 (D.N.J. Apr. 30, 2014) (quoting *MK Strategies, LLC v. Ann Taylor Stores Corp.*, 567 F. Supp. 2d 729, 737 (D.N.J. 2008)). Here, a more definite statement of facts beyond those that support the elements of Plaintiff's claim is not necessary.

Conclusion

Ms. Pennell welcomes the opportunity to defend her pleading, but Novo has shown no reasonable basis for their motion to dismiss.

Respectfully submitted,

s/ Parvin K. Aminolroaya

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CERTIFICATE OF SERVICE

I hereby certify that, on July 25, 2025, the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system, causing a notification of the filing to all counsel of record.

Dated: July 25, 2025

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